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IN THE

Supreme Court of the United States

OCTOBER TERM, 1968

No. 86

AMP INCORPORATED, *Petitioner,*

v.

WILBUR J. COHEN, Secretary of Health, Education and Welfare; and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

SUPPLEMENTAL BRIEF

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SUPPLEMENTAL BRIEF

This brief is submitted to call attention to matter not available at the time of petitioner's last filing.

The Solicitor General, on behalf of the United States, has filed a Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit, No. 343, this Term, to review the decision in *United States* v. *An Article of Drug* * * * *Bacto-Unidisk* * * *, 392 F.2d 21.

The Solicitor General, in his petition, comments on the decision in *AMP* v. *Gardner* and the relationship

between that decision and the *Bacto-Unidisk* decision. These comments are wholly inconsistent with statements made by the Solicitor General in his opposition to AMP's petition. Since the petition in *Bacto-Unidisk* was filed subsequent to the opposition in *AMP* it must be assumed that the *Bacto-Unidisk* petition contains the latest thoughts and opinions of the Solicitor General, arrived at upon further reflection and consideration.

In his opposition to AMP's petition, the Solicitor General stated that there was no conflict between the *AMP* and *Bacto-Unidisk* decisions and that the question involved in the *AMP* decision had no broad implications.[1] However, the main arguments advanced by the Solicitor General for granting his petition in *Bacto-Unidisk* are (1) that the *AMP* and *Bacto-Unidisk* decisions represent conflicting approaches to the

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[1] The Food and Drug Administration, however, has recognized the broad implications of the AMP decision. Note the article appended to petitioner's reply brief. In addition, a speech delivered July 16, 1968, by Paul A. Pumpian, Director, Office of Legislative and Governmental Services, Food and Drug Administration, contained the following statement:

> It may be noted that failure to obtain action on H.R. 10726 [The Medical Device Safety Act of 1967] may result in FDA's preclearance of some materials implanted in the human body under the existing "new drug" controls. This development has come about as the result of a decision of the United States Court of Appeals for the Second Circuit on February 13, 1968, captioned AMP Incorporated vs. John W. Gardner & James L. Goddard. * * * If certiorari is denied or if it is granted and the decision sustained, the Food and Drug Administration will have an excellent precedent to require preclearance of some important materials implanted in the body pursuant to our general authority to issue regulations for the enforcement of the Food, Drug, and Cosmetic Act.

interpretation of the Federal Food, Drug, and Cosmetic Act[2] and (2) that the issue[3] (drug vs. device) is

> . . . of vital importance to the public health and of general importance in the administration of the Federal Food, Drug, and Cosmetic Act.[4]

and that the particular judicial approach employed is

> . . . of great significance, not only in its application to the particular article at issue here, but in the general administration of the statute.[5]

Therefore, the opposition of the Solicitor General to AMP's petition should be considered as modified to the extent that it is inconsistent with the most recent statement of the Solicitor General as contained in the *Bacto-Unidisk* petition and as set forth above.

Respectfully submitted,

MARSHALL M. HOLCOMBE
Counsel for Petitioner

August 20, 1968

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[2] Page 15 of the petition states

> "[T]he decisions do represent a conflicting approach to the interpretation of the Act, rejecting common usage as determinative of what constitutes a drug."

[3] The issue is defined on page 13 of the petition as

> "The real question in the case is how to draw the line between 'drug' as defined in Section 201(g) [of the Federal Food, Drug, and Cosmetic Act] and 'device' which is defined in Section 201(h) as 'instruments, apparatus, and contrivances * * * intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease * * *'." (footnote omitted).

[4] Page 9.

[5] Page 16.